From: Sitesh Patel
To: Steve Wood (steve@seriousnutritionsolutions.com)
Subject: SOP"s
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Here is the next set. I will have to train you guys on this one so let set up a time when you are free.

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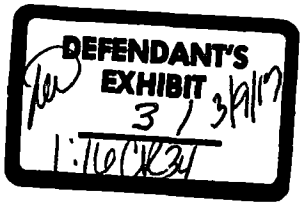

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I. PURPOSE

Batch production and control records must be prepared for each batch of dietary supplement produced in order to ensure the uniformity of finished products from lot to lot. This SOP describes the requirements for batch production and control records.

II. SCOPE

The requirements for batch production and control records apply to all batches of dietary supplement products that are produced.

III. RESPONSIBILITIES

A. Production Management and the Quality Control Unit shall ensure that batch production and control records are generated for each batch of dietary supplement product that is produced.

B. Production Management and the Quality Control Unit shall ensure that batch production and control records are maintained current as exact duplicates of the corresponding master production and control records.

IV. PROCEDURE

A. Batch production and control records must be prepared and followed for each batch of product, and these records must include complete information relating to the production, labeling, packaging, and specification sheet of each batch.

B. Batch production and control records must be an accurate reproduction of the corresponding master production and control record, and must include documentation that each significant step in the manufacturing process was accomplished, including:

1. Dates
2. Purchase order number.
3. Specific identification, including lot number as issued by manufacturer.
4. Quality control results (as outlined by specification test sheets)
5. Inspection of the packaging and labeling.
6. Any special notes of investigations or deviations from the described process

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C. Batch production and control records must be reviewed and approved by a qualified individual who will sign and date the batch records in a timely manner.

D. Any deviations from written and approved specifications, standards, test methods, or procedures must be recorded on the batch records.

E. For Finished product, sample must be taken and tested against specifications found on the specification sheet. QC/QA must record results and use in releasing procedure.

i. Results must be documented as actual results, ie Color of Capsule should be recorded as "Yellow/yellow" if that is the what the finished product shows.

ii. Packaging specifications must be recorded against specifications found on the specification sheet. Results recorded as what the actual finished product shows (ie "175cc PET blue bottle" as result)

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I. PURPOSE

This SOP defines the procedures that must be in place to establish specifications for all raw materials received.

II. SCOPE

The requirements of this SOP apply to all raw materials at main warehouse.

III. RESPONSIBILITIES

It is the responsibility of Warehouse Management, Production Management and the Quality Control Unit to ensure that the requirements of this SOP are enforced.

IV. PROCEDURE

A. Specification must be established for each individual raw material component received for warehousing.

B. Raw material ID code must be created. Can be created in Quickbooks.

C. Specifcation must state raw material ID code and Raw Material name.

D. Master Specification sheet must be created.

1. List Specifications established through COA.
2. Items include, organoleptic testing – smell, taste, color, etc.
3. Any lab analysis that can be performed.
4. Established specification minimum requirements taken from COA (ie Purity listed on COA)

E. Master Specification Sheet must be signed by QC/QA and filed away.

F. Upon receiving material, a copy of the Specification sheet must be made and sample of the material must be compared to the specifications listed on the sheet.

G. QA/QC will ensure all specifications are meet before releasing raw material.

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H. If all specifications are not met, material must be rejected and investigated for further action.

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I. PURPOSE

This SOP defines the procedures that must be in place to control materials received.

II. SCOPE

The requirements of this SOP apply to all raw materials, in-process materials and rework handled at main production facilities, as well as at satellite locations.

III. RESPONSIBILITIES

It is the responsibility of Warehouse Management, Production Management and the Quality Control Unit to ensure that the requirements of this SOP are enforced.

IV. PROCEDURE

A. Deliveries must be accompanied by a bill of lading (except for courier deliveries such as UPS) and a packing slip.

B. Match up the packing slip and bill of lading to the appropriate copy of the Purchase Order.

1. If there is no Purchase Order, check to see if the material is customer supplied or if the material is a sample sent for evaluation.

   i. If the material is customer supplied, indicate this on the packing slip and the bill of material.

   ii. If the material is a sample, it can be received without a purchase order, just be sure and to log and deliver to appropriate party.

2. If there is no Purchase Order and above doesn't apply, contact Purchasing Department.

3. If released by Purchasing, continue with procedure.

C. Compare the materials indicated on the packing slip with the materials on the Purchase Order.

1. If the materials do not match, contact Purchasing.

2. If all the materials match, continue with procedure.

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D. Count the number of containers included in the delivery and make sure they match the number of containers indicated on the bill of lading.

   1. If the number of containers do not match the number indicated on the bill of lading, contact purchasing.

   2. If the number of containers match the number indicated on the bill of lading, continue with procedure.

E. Check for any damage to the containers being delivered.

   1. If any damage is noticed, contact the Plant Manager.

   2. If there is no damage, continue with procedure.

F. Remove the delivery from the carrier (truck, etc.) and place in the designated receiving area within the Quarantine Area.

G. Sign the bill of lading and retain a copy as well as the packing slip and any other paperwork that was sent with the shipment. i.e.: Certificate of Analysis, Material Safety Data Sheets, etc.

H. Indicate the quantities received on the Purchase Order and initial and date your entries.

I. As soon as possible, at the first opportunity, log the information from the receipt into the Receiving Log Book.

J. Place all of the paperwork into a document jacket and place the document jacket on the top of the container or pallet received.

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I. PURPOSE

Dietary supplement products must bear an expiration date, or a statement of product shelf life which must be supported by data to assure that the product meets established specifications throughout the shelf life of the product. This SOP defines the requirements for establishing the shelf life of a dietary supplement product.

II. SCOPE

The requirements for establishing the shelf life of a finished product apply to all products produced by primary manufacturers, contract manufacturers and contract packagers.

III. RESPONSIBILITIES

A. Quality Assurance is responsible for ensuring that the requirements of this SOP are met, and that shelf life values are supported by data and rationale showing that the products meet specifications at their expiration dates.

B. Quality Assurance is responsible for ensuring that every finished product bears an expiration date or shelf life, as appropriate.

IV. PROCEDURE

A. Manufacturer

1. It is the responsibility of the manufacturer to maintain proper testing procedures for Shelf life testing.

2. Serious Nutrition Solutions will maintain testing records in yearly intervals on product shelf life testing from manufacturer.

A. Records will be stored along the master batch record in the MBR folder.

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I. PURPOSE

Master production and control records must be prepared for each dietary supplement product, and since all phases of production and control are governed by master production and control records, care must be exercised to ensure the accuracy of these records. An effective program for development and management of master production and control records will ensure production of safe products, and will guarantee uniformity from batch to batch. This SOP describes the requirements for master production and control records.

II. SCOPE

The requirements for master production and control records apply to all finished dietary supplement products.

III. RESPONSIBILITIES

A. Production Management and the Quality Control Unit must ensure that master production and control records are developed and maintained on file for each dietary supplement product.

B. Production Management and the Quality Control Unit must ensure that master production and control records are maintained current, and that any changes to these records are made in compliance with the requirements of the company's change control procedure to ensure that changes are properly communicated, and required approvals are obtained prior to implementing the changes.

IV. PROCEDURE

A. A master production and control record (e.g., manufacturing formula, raw material specifications, component specifications, finished product specifications) must be prepared for the manufacture of each product.

B. Master production and control records must include:

1. A complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s) and other specifications.

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2. The amount of each raw material used. Each batch must be formulated to provide not less than 100% of each claimed dietary ingredient throughout the shelf life of the product.

3. The name and weight or measure of each dietary ingredient per unit or portion, or per unit of weight or measure of the product.

4. A statement of the total weight or measure of any dietary supplement unit.

5. A specification sheet indicating all parameters used in manufacturing product (ie capsule weights, size, color, disintegration, powder color, taste, smell, etc).

6. A specification sheet indicating all parameters used for all product packaging including bottles, closures and labels.

7. Master copy of label to be used in production.

C. All master production and control records must be reviewed and approved by the Quality Control Unit prior to production of the first lot of a new product.

D. Specifications are to be obtained by manufacturer.

E. Master batch records should be filed individually per product, and filed with Product ID and Product Name on folder.

i. Establishing Spec Sheets for Capsules

A. Must establish specified Capsules Size

B. Must establish specified Capsule Color(s)

C. Must establish specified Capsule Printing

D. Must establish specified Visual inspection of Blend

E. Must establish specified Organoleptic Smell

F. Must establish range of weight per 10 capsules

ii. Establishing Spec Sheets for Powder Blends

A. Must establish specified Dry Color

B. Must establish specified Wet Color

C. Must establish specified Taste

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D. Must establish specified Smell

iii. Establishing Spec Sheets for Packaging

A. Must establish specified components used in packaging product.

I. I.e. Bottle size color, cotton, lid

B. Must establish specified label to be used on product. Master Production Record must specify exact label to be used. This will be compared with the actual product received.